

Notice of Allowability

Application No.

10/814,801

Examiner

Sharon Kennedy

Applicant(s)

DIONNE ET AL.

Art Unit

3767

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to Application filed March 31, 2004.
2. ☒ The allowed claim(s) is/are 1-24.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date 5-13-05
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413),
Paper No./Mail Date _____
7. ☐ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____

DETAILED ACTION

Allowable Subject Matter

Claims 1-24 are allowed.

The following is an examiner's statement of reasons for allowance: Applicant's claims are directed to an osmotic pump having a vent to release at least a portion of the osmotic agent. The purpose of the invention is set forth adequately in the background of the invention. It is beneficial to prevent the sudden release of a large amount of osmagent to the patient when an osmotic pump breaks in two. In addition, the venting prevents the breakage by preventing the pressure build up after the beneficial agent is released.

The patent to Ayer, US 6,270,787 is distinguished because holes 30, which at first glance could appear to be vents, function to allow the membrane plug 26 to swell into the holes creating a large frictional force between the membrane plug and the interior capsule walls which prevents membrane plug expulsion. Accordingly, holes 30 are not vents.

Regarding the patent to Theeuwes et al., US 5,312,389, port 21 is not a vent; it is the means by which syringes 20 and 60 may be filled with a beneficial agent. The agent is filled by injecting the beneficial agent through the fluid injection port 21. Theeuwes discloses vent 34, however, this is operable to vent the container 30 during filling. After attaching the container 30 to syringe 20, a liquid 40 is introduced into container 30 through port 33. Ambient pressure is maintained within container 30 by means of a vent 34 that extends through the wall of container 30. The vent 34 is filled

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with a material that is permeable to air but not permeable to the liquid. Accordingly, this reference does not disclose or anticipate a vent which is operative upon displacement of a semipermeable membrane.

The patent to Trautman, 2005/0095284, which has a later provisional filing date than the instant application, shows what appears to be a vent in figure 2C. However, orifice 216 merely allows fluid to pass through the membrane plug 200 to the osmotic agent and has the effect of accelerating the startup phase of the osmotic pump. There is no venting because upon adequate hydration/swelling of the columnar body 202 the orifice 216 becomes occluded which allows the osmotic function of the system to be fully activated.

The patent to Carr et al., US 6,508,808, discloses an osmotic delivery device with a vent 32 operative to vent from clearance 34 upon movement of valve 28 to clear the opening of the delivery orifice 18. Semipermeable membrane 30 is situated at the opposite end of these features. Assuming that delivery orifice 18 could be reasonably interpreted to be a vent, then this structure is similar to applicant's claim 20. However, claim 20 requires an exposing of the osmotic agent and release of at least a portion of the osmotic agent in the reservoir. See applicant's figure 4. In contrast, the Carr osmotic agent 24 is separated from orifice 18 by piston 20.

The patent to Peterson et al., US 6,840,931, discloses a vent hole 24 which is operative to vent the reservoir during filling thereof through fill hole 22. This is also distinguished from the invention because caps 26 are applied to seal the holes. The function of the caps is described in column 18, lines 13-29. "The caps 26, or means for

sealing the holes 22, 24 from the surrounding environment, may be fashioned from a material similar to that of the osmotic delivery system flow modulator body 21, and should sufficiently seal the fill hole 22 and vent hole 24 from the environment of use such that external liquids from the environment of use do not substantially leak or diffuse into the osmotic delivery system 40, and such that pressures generated from the osmotic agent 47 within the osmotic delivery system 40 do not substantially cause the beneficial agent 44 to leak out from the fill hole 22 or vent hole 24. The caps 26 may press fit or thread into the holes 22, 24."

The patent to Maruyama et al., US 5,997,902, also discloses a vent 39 which is operative to permit the escape of gases. This vent has nothing to do with the vent claimed in applicant's invention.

The patent to Magruder, US 5,234,693, also discloses vents 40a and 40b. These are fluid or fluid vapor passage means formed through the wall of the sleeve and are designed to communicate with the outside environment. They facilitate ventilation of air from space 32 during the implant procedure and provide another point of access to second section 12b for the fluid or fluid vapor environment.

Since none of the prior art discloses or suggests the claimed invention, the application is allowed.

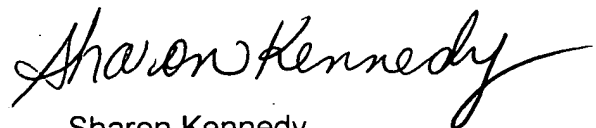
Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon Kennedy whose telephone number is 571/272-4948. The examiner can normally be reached on Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes, can be reached on 571/272-4959.

Information regarding the status of an application may be obtained by going to www.uspto.gov, clicking on "Status & IFW", entering the application number, and then clicking on one of the tabs to retrieve the appropriate information.

A handwritten signature in black ink that reads "Sharon Kennedy". The signature is written in a cursive, flowing style with a long horizontal stroke at the end.

Sharon Kennedy
Primary Examiner
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